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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/564,945	01/09/2007	Katherine Weilbaecher	60005161-0217	4085

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EXAMINER

RAE, CHARLESWORTH E

ART UNIT	PAPER NUMBER
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1611

MAIL DATE	DELIVERY MODE
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05/13/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/564,945	Applicant(s) WEILBAECHER ET AL.	
	Examiner CHARLESWORTH RAE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-42 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

Claims 1-42 are currently pending in this application and are the subject of the Office Action.

Restriction and Election Requirement

Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

This application contains the following inventions or groups of invention which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single species to which the claims must be restricted.

Group I. Claims 1-12, drawn to a method of treating, preventing or inhibiting tumor cell metastasis in a subject comprising administering in need of such therapy a therapeutically effective amount of an activated $\alpha_{II}\beta_3$ receptor antagonist. If this Group is elected, then the below Election of Species requirement is also required.

Group II. Claims 13-24, drawn to a method of preventing or inhibiting tumor non-metastatic cell formation in a subject in need of such therapy a therapeutically effective amount of an activated $\alpha_{II}\beta_3$ receptor antagonist. If this Group is elected, then the below Election of Species requirement is also required.

- Group III. Claims 25-36, drawn to a method of destroying a tumor in a subject comprising administering to the subject in need of such therapy a therapeutically effective amount of an activated $\alpha\text{IIb}\beta 3$ receptor antagonist. If this Group is elected, then the below Election of Species requirement is also required.
- Group IV. Claim 37, drawn to a method for treating, preventing or inhibiting tumor cell metastasis to bone in a subject comprising replacing substantially all bone marrow affected by tumor cell metastasis transplant in the subject, wherein said bone marrow is replaced with $\beta 3^{-1}$ bone marrow. If this Group is elected, then the below Election of Species requirement is also required.
- Group V. Claims 38-42, drawn to a method for treating, preventing or reversing tumor metastasis or formation comprising modulating $\beta 3$ integrin expression in a mammalian cell. If this Group is elected, then the below Election of Species requirement is also required.

The inventions represented above as Groups I-V do not relate to a general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, because they do not share the same or corresponding technical features. Specifically, the technical feature of Group I is the method of treating, preventing or inhibiting tumor cell metastasis in a subject comprising administering in need of such therapy a therapeutically effective amount of an activated $\alpha\text{IIb}\beta 3$ receptor antagonist; the technical

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feature of Group II is the method of preventing or inhibiting tumor non-metastatic cell formation in a subject in need of such therapy a therapeutically effective amount of an activated $\alpha_{II}\beta_3$ receptor antagonist; the technical feature of Group III is the method of destroying a tumor in a subject comprising administering to the subject in need of such therapy a therapeutically effective amount of an activated $\alpha_{II}\beta_3$ receptor antagonist; the technical feature of Group IV is the method for treating, preventing or inhibiting tumor cell metastasis to bone in a subject comprising replacing substantially all bone marrow affected by tumor cell metastasis transplant in the subject, wherein said bone marrow is replaced with β_3^{-1} bone marrow; and the technical feature of Group IV is the modulating of β_3 integrin expression in a mammalian cell. Thus, the requirement is proper as the inventions represented above as Groups I-II lack unity of invention under PCT Rule 13.1.

Species Election regarding Groups I-V

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. For example, the generic inventions encompass a heterogenous group tumors/tumor cells and of chemical agents. Each cancer cell line or tumor represent distinct morphologic characteristics. Similarly, each chemical species represent a unique therapeutic agent, which exhibit different/variable pharmacologic and pharmaceutical properties. The therapeutic effects to be achieved with these different chemical compounds would reasonably differ substantially depending on the specific compound, as well as the

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doses and duration of treatment, and the contemplated targeted cancer cell line or tumor. Thus, these species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Applicant is required to elect a single species from the below list for examination purposes:

1) a single chemically defined $\alpha\text{II}\beta\text{3}$ receptor antagonist compound, wherein each optional group is specifically indicated e.g. the compound recited in claim 11 (see specification page 8); and

2) a single specific cancer cell type or single specific tumor species as appropriate e.g. melanoma cells or melanoma (see specification, page 35, last para.).

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to the additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after election, applicant must indicate which are readable upon the elected

species (MPEP 809.02(a)). Claims 1, 13, 25, 37, and 38 are considered generic to the above species.

Inventorship Notice

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charlesworth Rae whose telephone number is 571-272-6029. The examiner can normally be reached between 9 a.m. to 5:30 p.m. Monday to Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have any questions on access to the Private PAIR system, contact the

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Electronic Business Center (EBC) at 800-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

10 May 2008

/C. R./

Examiner, Art Unit 1611

/Brian-Yong S Kwon/

Primary Examiner, Art Unit 1614